REMARKS/ARGUMENTS

In response to the Office Action mailed January 7, 2009, Applicants amend their application and request reconsideration in view of the amendments and the following remarks. In this amendment, Claim 1 is amended, no claims have been added, and no claims have been cancelled without prejudice so that Claims 1-4 and 6-7 are currently pending. No new matter has been introduced.

Claims 1-4 and 7 were rejected as being unpatentable over U.S. Patent Publication 2005/166841 to Robida (Robida). This rejection is respectfully traversed.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d,488,20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria.

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

> "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In *re Royka*, 490F.2d 981, 180 USPQ 580 (CCPA 1074). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In *re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C.

> 103, then any claim depending therefrom is nonobvious. In *re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)."

Robida discloses a clamping fixture for spray coating stent. Robida discloses there is a need for a device for holding a stent during a coating operation that supports the stent against the forces of the coating operation and that does not inhibit the coating process. Robida also discloses that stents may be coated with drug-loaded polymer coatings. Robida discloses a laundry list of therapeutic agents including the anti-proliferative rapamycin and cladribine. Robida also discloses that any of the agents may be combined.

Robida does disclose drug eluting stents and lists many different therapeutic agents. However, there is simply no motivation or reason as to why those two specific drugs should be combined or should have been combined. As set forth in Takeda below, simply listing compounds is not enough to make a new invention obvious in light thereof. The claimed invention even gives a dose range and this is simply not just a matter of experimentation. One skilled in the art would not simply just look at the list and pick two compounds to test. It is respectfully submitted that it is not obvious as the Examiner has asserted. Accordingly, reconsideration and withdrawal is respectfully requested.

> But here, unlike in KSR, the prior art did not provide "a finite number of identified, predictable solutions." Rather, it disclosed a broad selection of compounds any one of which could have been selected as the lead compound.
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> Takeda Chemical Industries, LTD. V. Alphapharm Pty., Ltd., 492 F. 3d 1350, 2007 U.S. App. LEXIS (Fed. Cir. 2009).

Claims 1-4 were rejected under 35 U.S.C. § 103(a) as being unpatentable over WO 01/87372 to Kopia et al. in view of U.S. Patent No. 5,516,781 to Morris et al. (Morris). Claims 6 and 7 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kopia in view of Morris and further in view of U.S. Patent Publication No. 2003/36794 to Ragheb et al. (Ragheb). These rejections are respectfully traversed.

Kopia discloses the local release of a combination of specific agents from a stent. The two agents are the anti-proliferative agent rapamycin and the anti-inflammatory agent dexamethasone. These drugs may also be delivered systemically.

Morris discloses a method of preventing or treating hyperproliferative vascular disease in a mammal by administering an antiproliferative effective amount of rapamycin alone or in combination with mycophenolic acid.

Ragheb discloses coated implantable medical devices. Various polymers may be utilized in the coating, including acrylic and fluropolymers.

Once again, there is simply no reason or motivation to select the claimed two compounds that can be gleaned from the references. Simply stated, there is no hint as to why to pick rapamycin and clardrabine, much less have a specific dose range. Accordingly, for all the reasons set forth herein, reconsideration and withdrawal of the rejection is respectfully requested.

Applicant would be grateful for the opportunity to conduct a telephonic or in-person interview if the Examiner believes it would be helpful in disposing of the present case.

Respectfully submitted,

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